

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA ex rel.)	
ROBERT A. FRY,)	
)	
Plaintiffs,)	
)	Civil Action: 3:03-0842
v.)	Hon. Aleta Trauger
)	Magistrate Judge Bryant
GUIDANT CORPORATION, its predecessor)	
Cardiac Pacemakers, Inc.,)	
a division of Eli Lilly and Company,)	
)	
Defendant.)	

DEFENDANT'S STATUS CONFERENCE MEMORANDUM

Pursuant to the parties' joint request, the Court has set a Status Conference in this matter for September 3, 2009 at 11:00 am. This memorandum is submitted by Defendant, Guidant Corporation ("Guidant"), to more fully describe the matters Guidant asks the Court to consider at the conference.

I. Rule 16 and This Conference

Among the matters specifically set forth in F.R.C.P. 16(c)(2) as appropriate for consideration at the status conference are the following:

F.R.C.P. 16(c)(2) Matters for Consideration:

At any pretrial conference, the court may consider and take appropriate action on the following matters:

(A) formulating and simplifying the issues, and eliminating frivolous claims or defenses;

...

(C) obtaining admissions and stipulations about facts and documents to avoid unnecessary proof, and ruling in advance on the admissibility of evidence;

(D) avoiding unnecessary proof and cumulative evidence, and limiting the use of testimony under Federal Rule of Evidence 702;

(E) determining the appropriateness and timing of summary adjudication under Rule 56;

...

(L) adopting special procedures for managing potentially difficult or protracted actions that may involve complex issues, multiple parties, difficult legal questions, or unusual proof problems;

...

(N) ordering the presentation of evidence early in the trial on a manageable issue that might, on the evidence, be the basis for a judgment as a matter of law under Rule 50(a) or a judgment on partial findings under Rule 52(c);

(O) establishing a reasonable limit on the time allowed to present evidence; and

(P) facilitating in other ways the just, speedy, and inexpensive disposition of the action.

With fact discovery in this matter now largely completed, Guidant believes that it is appropriate to seek the Court's guidance in the orderly presentation of dispositive motions in this complex matter and, should these motions not fully dispose of the case, in presenting the case for trial.

II. The Case as it Currently Stands

Summarizing their allegations most broadly, plaintiffs claim Guidant

defrauded the federal government by concealing and/or refusing to pay credits due hospitals replacing Guidant implantable cardiac devices (ICDs) for Medicare and VA patients. This scheme, plaintiffs allege, resulted in injury to the federal health care programs providing benefits to those patients. Guidant denies the allegations.

The parties have pursued extensive written, documentary and testimonial discovery. Through this process, which will conclude October 30th, plaintiffs identified 55,127 ICD replacement procedures from more than 320,000 disclosed in discovery as the basis of their False Claims Act case. Guidant believes that the Court's assistance at this point is critical in determining how these 55,127 individual alleged false claims will be resolved. Specifically, Guidant would like to discuss how an efficient and manageable dispositive motion process could be implemented, and includes its suggestion below in Section III. Should the case not be fully resolved through motion, Guidant believes that the Court's early engagement could fashion an efficient trial plan for any claims that remain after summary judgment.

III. Threshold Dispositive Issues

The False Claims case alleged by plaintiffs here is expansive and complicated. The 55,127 ICD replacement procedures allegedly triggered Guidant's submission of a like number of false claims occurred over 15 years, in all 50 states and in Puerto Rico, in hospitals both public and private, and implicate a variety of different government reimbursement systems. In the absence of reasonable procedures to streamline this sprawling case, both the parties and the Court will

face huge challenges in presenting and resolving the matter. Guidant believes that the most appropriate and efficient way to manage the difficult legal questions and unusual proof problems plaintiffs' case creates is to address threshold legal issues that are generally applicable to all of plaintiffs' claims. To this end, Guidant seeks to file motions for summary judgment at the close of fact discovery on these issues. Guidant believes that the case can be fully adjudicated through such motions. If, however, the Court concludes that some portion of the case remains following ruling on these motions, Guidant believes that the case may still have been narrowed and refined substantially by the dispositive motion process. Because the method, scope, trial time and evidence presentation at trial is likely to be lengthy and involved, Guidant believes early coordination with the Court's input is, from a practical standpoint, necessary.

Among the threshold, cross-cutting issues implicated by plaintiffs' case are the following:

1. Falsity. Guidant believes plaintiffs cannot show falsity as a matter of law. Plaintiffs allege that by failing to issue credits Guidant caused hospitals to submit payment claims to the federal health care programs that were false because the cost of the device stated in the claims was not the net cost, and was higher than it should have been. *See e.g.,* United States' Response to Interrogatory Numbers 22 and 23. Guidant believes that the undisputed facts established through discovery concerning the invoice process, the terms of Guidant's warranty programs, and the process by which hospitals submit claims for payment to the government, including the undisputed facts concerning Patients A-E identified in the Second Amended Complaint, render the question whether any of the claims at issue in this litigation could have been false as a matter of law appropriate for summary disposition.

2. Causation and Materiality. Guidant believes plaintiffs cannot establish causation, or show that the alleged conduct was material to payments made by the federal health care programs. Plaintiffs allege Guidant's failure to issue credits caused hospitals to submit false claims for payment. Guidant believes that the undisputed facts show that neither Guidant's statements nor conduct caused hospitals to submit false claims to the government; in fact, the hospitals' charges were unaffected by Guidant's conduct. With respect to the closely related issue of materiality, even if summary judgment is not granted as to causation, Guidant believes that the undisputed facts show that no statement it made or caused to be made to the government was "capable of influencing the [government's] [payment] decision." *United States ex rel. A+ Homecare, Inc. v. Medshares Management Group, Inc.*, 400 F.3d 428, 443, 445 (6th Cir. 2005).

3. Knowledge. Guidant believes the evidence is undisputed that the hospitals plaintiffs claim were unaware of Guidant's credit programs were knowledgeable about those programs and benefited from them. Plaintiffs have alleged that hospitals were unaware of the availability of replacement device credits from Guidant as well as from other ICD manufacturers whose credit programs were substantially similar to Guidant's. (For example, Relator testified that "[The warranty programs] were about the same. There's not much difference. They're all universally about the same." Deposition of Robert Fry, 52:1-5.) Guidant believes that the undisputed facts will show that the hospitals were aware of the existence of warranties and that virtually all of them applied for and received ICD replacement credits from Guidant.

Guidant believes that addressing these, and other, threshold legal issues common to plaintiffs' claims at the conclusion of fact discovery will serve the purposes enumerated in Rule 16, *supra*, by disposing of the case in its entirety or, short of that, significantly narrowing the scope of issues to be resolved, reducing the complexity and expense of expert discovery, reducing the number of pre-trial issues that will require the Court's decision, and narrowing the scope of issues to be addressed at trial. Plaintiffs' burden is to establish all elements of a false claims act violation for each false claim they allege. The proof necessary to sustain the burden

will, in the absence of this suggested case management, be highly fact specific based on the nature, time frame and amount of the claim, whether the claim was submitted by a private or government hospital, the contractual relationship between Guidant and the hospital, the hospital's processing of the claim and the form of Medicare reimbursement utilized for that type of claim for that particular year, and the hospital's specific action, knowledge and decision relating to that claim. Plaintiffs' necessary proof of damages will entail a complex and expensive analysis of the applicable and evolving government payment rules and regulations. To the extent that summary judgment disposes of categories of claims based on the threshold legal issues that cut across the highly fact specific individual alleged false claims, the scope of expert discovery and the issues to be resolved at trial will be narrowed and settlement discussions will be facilitated.

IV. Issues Suggested to be Addressed at the Conference

- A.** Timing and structure of summary judgment motions
- B.** Whether the existing case management order should be modified to allow focus on summary judgment before incurring the burden and expense of expert discovery.
- C.** Timing and structure of mediation pursuant to the Court's customary orders regarding same, if needed.
- D.** Sequencing of expert discovery, final pre-trial and trial, if needed.

s/ David L. Douglass
David L. Douglass (*pro hac vice*)
Jennifer H. McGee (*pro hac vice*)
SHOOK HARDY & BACON L.L.P.
600 14th Street, NW, Suite 800
Washington, DC 20005-2004
Telephone: (202) 783-8400

Facsimile: (202) 783-4211
E-mail: ddouglass@shb.com
jmcgee@shb.com

Michael L. Koon (*pro hac vice*)
Carol A. Poindexter (*pro hac vice*)
SHOOK, HARDY & BACON, L.L.P.
2555 Grand Boulevard
Kansas City, MO 64108
Telephone: (816) 559-2285
Facsimile: (816) 421-5547
E-mail: mkoon@shb.com
cpoindexter@shb.com

Jennifer L. Weaver (BPR # 020142)
WALLER LANSDEN DORTCH & DAVIS,
LLP
511 Union Street, Suite 2700
Nashville, Tennessee 37219-8966
Tel. (615) 850-8116
Fax. (615) 244-6804
E-mail: jennifer.weaver@wallerlaw.com

Attorneys for Defendant Guidant Corporation

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing was sent to the following persons via the Court's electronic filing system on this 28th day of August, 2009:

Ernest Clayton Yates
Yates & Mancini, LLC
311 S Second Street; Suite 102
Fort Pierce, Florida 34950
clay@yatesandmancini.com

David B. Wiseman
Department of Justice
Civil Div./Commercial Litigation Branch
P O Box 261; Ben Franklin Station
Washington, DC 20044
david.wiseman@usdoj.gov

R. Kevin Fisher
Fisher & Krekorian
225 Santa Monica Blvd., 12th Floor
Santa Monica, CA 90401
rkf@fkslaw.net

Stephanie A. Morse
Assistant Attorney General
Medicaid Fraud Control Unit
444 Brickell Avenue, Suite 650
Miami, FL 33131
Stephanie.Morse@myfloridalegal.com

Michael Kevin Bassham
Peter M. Coughlan
Office of the Attorney General
425 Fifth Avenue North; Second Floor
Nashville, Tennessee 37423
michael.bassham@state.tn.us
peter.coughlan@state.tn.us

Richard A. Fisher
Richard Fisher Law Office
1510 Stuart Road, Suite 210
Cleveland, Tennessee 37312
richardfisher4@cs.com

Mona Lisa Wallace
John S. Hughes
Wallace and Graham, P.A.
525 North Main Street
Salisbury, North Carolina 28145
mwallace@wallacegraham.com

Theodore J. Leopold
Ricci Leopold, PA
2925 PGA Blvd., Suite 200
Palm Beach Gardens, Florida 33410
Tleopold@riccilaw.com

Michael L. Roden
Ellen Bowden McIntyre
Office of the United States Attorney
Suite A-961, 110 Ninth Avenue South
Nashville, Tennessee 37203-3870
michael.roden@usdoj.gov
ellen.bowden2@usdoj.gov

Dennis T. Fenwick
Office of the Attorney General
Bureau of Medi-Cal Fraud & Elder Abuse
State of California
1425 River Park Drive, Suite 300
Sacramento, CA 95815
dennis.fenwick@doj.ca.gov

s/ David T. Fischer